

Notice of Allowability	Application No.	Applicant(s)	
	10/511,669	BRINGE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment and remarks filed 1/20/09 and telephonic interview of 3/5/09.
2. ☒ The allowed claim(s) is/are 1,2,5-13,15,17-25,31-34,36,37 and 40-46.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>1/20/09; p2 of 10/21/05</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20090309</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
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**ACKNOWLEDGEMENT TO AMENDMENT, REMRAKS, IDS AND THE STATUS OF
THE CLAIMS**

1. The amendment, remarks and information disclosure statement filed 01/20/09 are acknowledged, entered and considered. Claims 12, 15, 17-20, 24, 33 and 34 have been amended and claim 16, 26 and 27 have been canceled. Claims 1-15, 17-25 and 28-55 are now pending in the application of which claims 1-11, 14, 28-32 and 35-55 were withdrawn previously as non-elected invention. The rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment and remarks filed 1/20/09.

**ALLOWABLE PRODUCT, REJOINDER OF ALL PREVIOUSLY WITHDRAWN
PROCESS CLAIMS**

2. Claims 12, 13-15, 17-25 and 31-34 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 1-11 are directed to the process of making, and claims 36, 37 and 41-46 are directed to the process of using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 10/01/07 are hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claims

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including all the limitations of an allowable product claim or rejoined process claim are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

4. Authorization for this examiner's amendment was given in a telephone interview with Ron J. Laby on 03/05-09.

5. The application has been amended as follows

Replace the claims as follows:

1. (Currently amended) A method of preparing a foodstuff, comprising the steps of:
 - (a) obtaining a selected foodstuff; and
 - (b) adding the composition of claim 12 ~~isolated oil-associated protein~~ to the foodstuff, wherein the consumption of an effective amount of the foodstuff lowers ~~decreases~~ the serum cholesterol levels of a

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subject in need thereof.

2. (Currently amended) The method of claim 1, further comprising adding at least one compound selected from the group consisting of a saponin, a phytoestrogen, ~~a phospholipid~~, and a carbohydrate substantially resistant to digestion.

3-4. (Canceled).

5. The method of claim 1, wherein the foodstuff is soy-based.

6. (Currently amended) The method of claim 1, wherein the foodstuff lacks oleosin ~~oil body associated protein~~ prior to the step of adding.

7. (Currently amended) The method of claim 1, wherein the foodstuff comprises oleosin ~~oil body associated protein~~ prior to the step of adding.

8. The method of claim 5, wherein the foodstuff is selected from the group consisting of soy flour, soy grit, soy meal, soy flakes, soy milk powder, soy protein concentrate, soy protein isolate and isolated soy polypeptide.

9. The method of claim 8, wherein the soy protein isolate is a high molecular weight fraction of a soy material treated with a protease.

10. (Currently amended) The method of claim 8, wherein the isolated soy polypeptide comprises β -conglycinin ~~or a fragment thereof~~.

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11. (Currently amended) The method of claim 8, wherein the isolated soy polypeptide is glycinin or a fragment thereof.

12. (Previously presented) A composition for lowering serum cholesterol levels comprising:

(a) glycinin and/or β -conglycinin,

(b) oleosin, wherein the composition comprises at least 5% oleosin; and

(c) phospholipid, wherein the phospholipid comprises less than 2% weight percent of the composition.

13. (Previously presented) The composition of claim 12, wherein the glycinin or β -conglycinin is at least partially hydrolyzed by an enzyme or a mixture of enzymes.

14. (Canceled).

15. (Currently amended) The composition of claim 12, further defined as comprising β -conglycinin and purified oleosin.

16. (Canceled).

17. (Previously presented) The composition of claim 12, wherein the composition comprises from about 5% to about 10% oleosin.

18. (Previously presented) The composition of claim 12, wherein the composition comprises greater than about 10% oleosin.

19. (Previously presented) The composition of claim 12, wherein the composition comprises about 30% to about 50% oleosin.

20. (Previously presented) The composition of claim 12, further comprising at least one additive compound, wherein the additive compound is selected from the group consisting of a saponin, a phytoestrogen, and a carbohydrate substantially resistant to digestion.

21. (Previously presented) The composition of claim 20, wherein the phytoestrogen comprises an isoflavone.

22. (Previously presented) The composition of claim 21, wherein the isoflavone is selected from the group consisting of genistein, diadzein, equol, biochanin A, formononetin, and their respective naturally occurring glucosides and glucoside conjugates.

23. (Previously presented) The composition of claim 20, wherein the carbohydrate is selected from the group consisting of high amylose starch, oligofructose, and soy cotyledon fiber.

24. (Previously presented) The composition of claim 12 wherein the phospholipid is selected from the group consisting of lecithin, lyso-lecithin, and lecithin with a modified fatty acid composition.

25. (Previously presented) The composition of claim 20, wherein the saponin is selected from the group consisting of soy saponin A, saponin B, saponin E, sapogenol A, sapogenol B, and sapogenol E.

26-30. (Canceled).

31. The composition of claim 12, wherein the glycinin is the basic subunit of glycinin.

32. The composition of claim 31, wherein the basic subunit of glycinin is the β -1b subunit.

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33. (Previously presented) The composition of claim 12, wherein the β -conglycinin is the α' subunit thereof.

34. (Currently amended) The composition of claim 12, further defined as comprising more than 40% β -conglycinin.

35. (Canceled).

36. (Currently amended) A method for lowering serum cholesterol levels ~~the treatment or prevention of hypercholesterolemia~~ comprising the steps of:

- (a) adding the composition of claim 12 ~~oil body associated protein~~ to a selected foodstuff; and
- (b) providing the foodstuff to a subject in need thereof in a quantity sufficient to lower serum cholesterol levels ~~to treat or prevent hypercholesterolemia~~.

37. (Currently amended) The method of claim 36, further comprising adding at least one compound to the foodstuff selected from the group consisting of a saponin, a phytoestrogen, a phospholipid, and a carbohydrate substantially resistant to digestion.

38-39. (Canceled).

40. The method of claim 36, wherein the foodstuff is a soy-based.

41. (Currently amended) The method of claim 36, wherein the foodstuff lacks oleosin ~~oil body associated body protein~~ prior to the step of adding.

42. (Currently amended) The method of claim 36, wherein the foodstuff comprises oleosin ~~oil body associated protein~~ prior to the step of adding.

43. The method of claim 42, wherein the foodstuff is selected from the group consisting of soy flour, soy grit, soy meal, soy flakes, soy milk powder, soy protein concentrate, soy protein isolate and isolated soy polypeptide.

44. The method of claim 43, wherein the soy protein isolate is a high molecular weight fraction of a soy material treated with a protease.

45. (Currently amended) The method of claim 43 wherein the isolated soy polypeptide comprises β -conglycinin. ~~or a fragment thereof~~

46. (Currently amended) The method of claim 43 wherein the isolated soy polypeptide is glycinin. ~~or a fragment thereof~~

47-55 (Canceled).

CONCLUSION AND FUTURE CORRESPONDANCE

6. Claims 1, 2, 5-13, 15, 17-25, 31-34, 36, 37 and 40-46 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657